DETAILED ACTION

Applicant's election without traverse of Group II, claims 141-167, and the species found in claim 153 wherein M is H, in the reply filed on March 21, 2008 is acknowledged. The amendment filed March 21, 2008, wherein claims 109-140, 149, and 154 are canceled, is acknowledged. Claims 141-148, 150-153, and 155-167 are pending. Claims 155-161 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 21, 2008. Claims 141-148, 150-153, and 162-167 are examined on the merits herein.

In the response to restriction dated March 21, 2008, Applicant did not indicate which claims read on the elected species. The examiner contacted Mr. Leonard on April 28, 2008 and inquired whether claims 163, 164, 166, and 167 read on the elected species (see attached interview summary). As of May 8, 2008, Mr. Leonard had not returned the examiner's call. Thus, claims 163, 164, 166, and 167 will be examined as if they do read on the elected species.

This application is a national stage entry of International Application No. PCT/NZ05/00052, filed March 22, 2005, which claims priority to New Zealand Applications No. 531866, filed on March 22, 2004 and 537941, filed January 28, 2005. The certified copies of the priority applications have been filed with the instant Application.

In the response to restriction dated March 21, 2008, Applicant states that claims 153-161 have been amended to include an omitted hydroxyl substituent of the carbohydrate function (F). Claims 153-161 appear to recite the same structures as were present in the claim set submitted September 22, 2006 and claims 153-161 are listed as (previously presented) and not as (currently amended). Clarification is requested.

The document "Derwent Abstract Accession No. 2004-449665142 A25 B04 (A96), of the IDS dated September 22, 2006, October 16, 2006, and January 12, 2007, was not considered because it has not been provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 141-148, 150-152, and 162-167 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number

of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

The claims herein are drawn to the use of any agents represented by "F-S_1-S_2-L," wherein F is a carbohydrate and S_1 and S_2 are spacer groups. These are not further defined in the specification. Thus, the recitation in the claims are deemed to a broad genus of any compounds containing a carbohydrate and a spacer group.

The specification as originally filed does not provide adequate support for the generic claims herein. The specification merely describes 9 compounds (pages 5-7), each of which contain only 1-5 glycosyl residues and all of which contain, as S_1-S_2-L, substantially the same moiety, as shown in claim 1, which differs only by carbon chain

length. Both "carbohydrate" and "spacer group" are extremely broad terms which encompass a nearly infinite number of possible combinations, the vast majority of which are not described in the specification. The skilled artisan would also understand that, within that large number of combinations, are a number of embodiments of immense strructural variation that would not be suitable for the claimed method, given the fact that any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physical, chemical, physiological effects and functions.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 141-148, 150-152, and 162-167 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any carbohydrate and/or spacer group. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of the compounds on pages 5-7 of the specification, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984)

(affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 141-148, 150-153, and 162-167 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of the particular constructs B_{tri}-sp-Ad-DOPE, A_{tri}-sp-Ad-DOPE, H_{tri}-sp-Ad-DOPE, A_{tri}-spsp_1-Ad-DOPE, and A_{tri}-sp-Ad-DSPE for incorporation into the lipid bilayer of a cell, does not reasonably provide enablement for the use of any construct of the formula F-S_1-S_2-L for the same, and does not reasonably provide enablement for effecting any positive or negative qualitative and/or quantitative changes in the surface antigens expressed by a cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not

be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method of effecting changes in the surface antigens expressed by a cell by contacting the cell with a construct of the formula $F\text{-}S_1\text{-}S_2\text{-}L$, wherein F is a carbohydrate and S_1 and S_2 are spacer groups. "Carbohydrate" and "spacer group" are not further defined in the specification and these encompass a very large number of possible moieties, having immense structural variation. For example, "carbohydrate" can encompass monosaccharides, oligosaccharides, and polysaccharides such as cellulose. "Spacer group" is not defined in the specification and thus could be any moiety, including large and complex structures. Furthermore, it is unclear which changes are being effected. Thus, the claims taken together with the

specification imply that any construct of the formula F-S_1-S_2-L can be used to effect any quantitative and/or qualitative changes in the surface antigens expressed by a cell, including increasing or decreasing the number and types of antigens expressed by a cell.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

As mentioned in the specification, insertion of GPI linked protein into membranes, which effects change in the surface antigens expressed by a cell, is known.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification states that synthetic glycolipid-based antigens can be incorporated into cell membranes, thus effecting changes in the surface antigens expressed by the cell. Thus, the invention is understood to involve insertion of antigens into a cell membrane, which would increase the number of antigens or add a new antigen that was previously absent. Under this understanding of the invention, the claimed method could not decrease the number or type of antigens expressed. Thus, the claims are not enabled for effecting negative change in the antigens expressed. Furthermore, the claims are not enabled for the generic "effecting change" with no description of which changes are effected.

The specification (page 52, Table 22) also states that, of the nine glycolipids tested, four were not suitable for use in the transformation of cells. These nine exemplary compounds are a very small sampling of the entire scope of F-S_1-S_2-L, as

discussed above. Given that nearly half of this very small sampling of the entire scope of claim 141 is not suitable for use in the transformation of cells, the skilled artisan would not expect the entire scope of claimed constructs to be effective.

The specification (page 2) states the importance of water solubility of the constructs that can incorporate into lipid bi-layers. The skilled artisan would understand that the term "carbohydrate" encompasses many different moieties, including large polysaccharides, that would not be suitable for the purpose described in the specification. The skilled artisan would also understand that "spacer group" can encompass a nearly infinite number of moieties, many of which would also not be suitable for the disclosed purpose.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the breadth of the claims and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Claims 141-148, 150-153, and 162-167 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 141 (and dependent claims) is drawn to the use of a synthetic molecule construct of the structure F-S_1-S_2-L. This structure is vague and indefinite because

none of F, S_1, or S_2 has been defined with clarity and it is unclear whether these are covalently bonded or associated in some other way, and where the location of the possible bonds between F, S_1, S_2 and L is. Examples are included in the specification but the examples represent a very small fraction of the entire scope of the claims.

Claim 141 (and dependent claims) is drawn to a method of effecting qualitative and/or quantitative changes in the surface antigens expressed by a cell or multi-cellular structure. The specification does not define the changes that are effected. The specification does state that one object of the invention is to incorporate the F-S_1-S_2-L molecule into the lipid bilayer of a cell, but that is not a definition of the vague and indefinite recitation "effecting qualitative and/or quantitative changes in the surface antigens expressed by a cell or multi-cellular structure."

Claim 141 (and dependent claims) recites the limitation "S_1-S_2 is a spacer linking F to L." S_1 and S_2 are not defined in the specification and thus the skilled artisan would not be aware of the metes and bounds of the claim. Note that examples and preferred embodiments are not a definition.

Claim 143 depends from claim 141 and recites the limitation "the water soluble synthetic membrane anchor." "Water soluble" has been removed from claim 141. There is insufficient antecedent basis for this limitation in the claim. Similarly, claims 144, 145, 146 (and all dependent claims) are rejected.

Claim 153 recites the limitation "M is typically H, but may be replaced by another monovalent cation such as Na^+, K^+, or NH_4^+." "Typically" is a narrower statement of the broader limitation. A broad range or limitation together with a narrow range or limitation

that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claim 163 (and dependent claims) is drawn to a method "where F is an attachment molecule." "Attachment molecule" is not defined in the specification and the skilled artisan would not be aware of the metes and bounds of the claim. Claim 163 further states that the attachment molecule "has an affinity for a component expressed on the epithelial cells or the extra-cellulose matrix of the endometrium." It is unclear which molecules meet this limitation and the specification provides no guidance for such.

Claim 166 (and dependent claims) is drawn to a method wherein "F is a ligand for a binding molecule where the presence of the binding molecule is diagnostic for a pathological condition." The specification does not provide any guidance for which

compounds meet the limitation. Thus the skilled artisan would not be aware of the metes and bounds of the claim.

Claim 167 is drawn to a method wherein "F is a ligand for an antibody (immunoglobulin)." The specification does not provide any guidance for which compounds meet the limitation. Thus the skilled artisan would not be aware of the metes and bounds of the claim.

Note that the elected species wherein M is H, is seen to be free of prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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